UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

SOLVAY PHARMACEUTICALS, INC., Plaintiff, v. ETHEX CORPORATION, KV PHARMACEUTICAL COMPANY, Defendants.	Civil No. 03-2836 (JRT/FLN) **MEMORANDUM OPINION AND ORDER DENYING DEFENDANTS' SUMMARY JUDGMENT MOTION**

John B. Gordon and Peter J. Goss, **FAEGRE & BENSON LLP**, 90 South Seventh Street, Suite 2200, Minneapolis, MN 55402; Lisa Horvath Shub and Saul H. Perloff, **FULBRIGHT & JAWORSKI LLP**, 300 Convent Street, Suite 2200, San Antonio, TX 78205; Marc B. Collier, **FULBRIGHT & JAWORSKI – AUSTIN**, 600 Congress Avenue, Suite 2400, Austin, TX 78701, for plaintiff.

William Z. Pentelovitch and Dawn C. Van Tassel, **MASLON EDELMAN BORMAN & BRAND, LLP**, 3300 Wells Fargo Center, 90 South Seventh Street, Minneapolis, MN 55402; and Thomas C. Morrison and Robert W. Lehrburger, **PATTERSON BELKNAP WEBB & TYLER LLP**, 1133 Avenue of the Americas, New York, NY 10036, for defendants.

Plaintiff Solvay Pharmaceuticals, Inc. ("Solvay") brought this lawsuit against defendants Ethex Corporation and KV Pharmaceutical Company (collectively, "Ethex"), asserting claims under the federal Lanham Act and Minnesota fraud and consumer protection statutes. Ethex now moves for summary judgment on Solvay's remaining

claims, found in Counts1 through 5 of the complaint.[1] For the following reasons, the Court denies the motion.

BACKGROUND

Solvay produces a pancreatic enzyme supplement under the trademark Creon. Pancreatic enzymes supplements are used by patients who have a shortage of natural digestive enzymes, such as people suffering from pancreatitis or cystic fibrosis. The active ingredient in these products is pancrelipase, an extract derived from pig pancreases that contains primary lipase, protease, and amylase, the three principal enzymes that a healthy pancreas secretes and that are critical to digestion. Solvay's current line of pancreatic enzyme supplements includes Creon 5, Creon 10, and Creon 20, based upon how many units of the lipase enzyme each product contains. Ethex manufactures and markets a competing line of pancreatic enzyme supplements under the trademark Pangestyme. Ethex promotes Pangestyme as a lower-priced "generic" alternative to Creon.

Prescription pancreatic enzyme supplements are, like any other drug, subject to FDA regulation. In 1995, the FDA declared that all pancreatic enzyme drugs would require the submission and approval of a "new drug application" ("NDA") or an "abbreviated new drug application" ("ANDA") beginning in April 2008, but permitted

[1] The Court previously dismissed Solvay's claim for a declaratory judgment, and also dismissed Solvay's Lanham Act claims to the extent they were based on Ethex's advertisements stating that Pangestyme is "high quality," "safer or more effective than Creon," "safer or more effective than" competing enzymes because of its enteric coating, "safer or more effective than" competing enzymes because it is made in the United States, and statements that Pangestyme is endorsed or approved by the Cystic Fibrosis Foundation. *See* Docket Nos. 39, 190.

such drugs to remain on the market during the approval process. *See* 69 Fed. Reg. 23410 (Apr. 28, 2004).

The FDA has not set standards for pancreatic enzyme supplements. Instead, the United States Pharmacopoeia ("USP") standards govern the strength, quality, and purity of these supplements. According to USP standards, pancrelipase delayed-release capsules, including the enzyme supplements at issue in this lawsuit, must contain lipase levels that are no less than 90% and no greater than 165% of the labeled strength, and the amylase and protease levels must be no less than 90% of the labeled strength.

Ethex markets Pangestyme as a generic equivalent of Creon. Ethex has used terms referencing Creon, including "generic," "compare to," and "alternative" in advertisements for Pangestyme. In addition, Ethex named its various forms of Pangestyme to correspond to forms of Creon. For example, Pangestyme-CN10 is meant to correspond to Creon 10. A review and comparison of the labels for Pangestyme-CN10 and Creon 10 shows that both drugs contain the same active ingredients in the same amounts. Ethex worked to have major drug information databases characterize Pangestyme as a generic substitute for Creon. As a result, when some pharmacists were presented with a Creon prescription, a message in the computer database would alert the pharmacist to the fact that Pangestyme could be substituted as an alternative to Creon. Ethex has also advertised that Pangestyme, like Creon, "meets all applicable USP standards," and that Pangestyme, like Creon, has a "release profile" at a pH of 5.5.

Ethex has not, however, expressly advertised that Pangestyme is "bioequivalent," "pharmaceutically equivalent" or "therapeutically equivalent" to Creon, which have been

defined by the FDA.[2] Nor has Ethex advertised that Pangestyme is approved by the FDA, or that Pangestyme is listed in the FDA's "Orange Book," which lists all NDA approved drugs along with therapeutic equivalence determinations. Solvay brought this lawsuit in April 2003, alleging that Ethex's advertising of Pangestyme is false and misleading under the Lanham Act and Minnesota state law. Ethex moves for summary judgment on Solvay's claims.

ANALYSIS

I. Summary Judgment Standard

Summary judgment is appropriate in the absence of any genuine issue of material fact and when the moving party can demonstrate that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). A fact is material if it might affect the outcome of the suit, and a dispute is genuine if the evidence is such that it could cause a reasonable jury to return a verdict for either party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). A court considering a motion for summary judgment must view all of the facts in the light most favorable to the non-moving party and give that party the benefit of all reasonable inferences that can be drawn from the facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

[2] According to the FDA, two drugs are "bioequivalent" if they do not have significantly different rates and extent of absorption in the body. 21 U.S.C. § 355(j)(8)(B); 21 C.F.R. § 320.1(f); Introduction to Approved Drug Products with Therapeutic Equivalence Evaluations, *available at* www.fda.gov/cder/ob. "Pharmaceutically equivalent" means that two drugs have the same active ingredients, strength, and dosage. 21 C.F.R. § 320.1(c); Introduction to Approved Drug Products with Therapeutic Equivalence Evaluations, *available at* www.fda.gov/cder/ob. Drugs are "therapeutically equivalent" if they are both "pharmaceutically equivalent" and "bioequivalent." *Id.* at § 355(j)(2)(A)(i)-(viii).

II. Lanham Act and Minnesota Consumer Protection Laws

The Lanham Act provides a civil remedy for a plaintiff who is injured by a defendant's false or deceptive advertising. *See* 15 U.S.C. § 1124(a)(1). To prevail on a claim under the Lanham Act, a plaintiff must establish that: (1) the defendant made false statements of fact about its own products, or the plaintiff's products, in an advertisement; (2) the advertising actually deceived or tended to deceive a substantial segment of its audience; (3) the deception is material because it is likely to influence buying decisions; (4) the defendant caused falsely advertised goods to enter interstate commerce; and (5) that the plaintiff was injured or is likely to be injured as a result. *Lenscrafters, Inc. v. Vision World*, 943 F. Supp. 1481, 1488 (D. Minn. 1996) (citing *Alternative Pioneering v. Direct Innovative Products*, 822 F. Supp. 1437, 1441-42 (D. Minn. 1993)). False statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA. *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F. Supp. 2d 967, 974 (E.D. Wis. 2005) (citing *Ethex Corp. v. First Horizon Pharm. Corp*., 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002)). Claims under Minnesota law require the same analysis as claims under the Lanham Act. *See Daimlerchrysler AG v. Bloom*, 315 F.3d 932, 936, n.3 (8th Cir. 2003). As such, the Court analyzes these claims together, using the same standards.

The plaintiff can satisfy its burden as to the first factor by demonstrating that the defendant made statements of fact regarding its own products, or the plaintiff's products, which are either literally false, or are literally true but likely to mislead customers.

Lenscrafters, 943 F. Supp. at 1488 *citing Alternative Pioneering*, 822 F. Supp. at 1442; *Johnson & Johnson-Merck v. Rhone-Poulenc Rorer*, 19 F.3d 125, 129 (3d Cir. 1994). To determine whether a particular representation is literally false, it must be analyzed with its full context. *United Industries Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998). Whether an advertisement is literally false presents a question of fact. *Lenscafters*, 943 F. Supp. at 1488, (citing *Johnson & Johnson v. GAC Int'l Inc.*, 862 F.2d 975, 979 (2d Cir. 1988)).

When advertising is alleged to be literally true yet misleading, the challenging party bears the burden of proving actual deception by a preponderance of the evidence; the challenging party must show how consumers actually react. *Id.* at 1488-89, *citing Sandoz Pharms. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 228-229 (3d Cir. 1990). The challenging party satisfies its burden by producing evidence of actual consumer reaction to the challenged advertising, which can take the form of circumstantial evidence, such as consumer surveys, consumer reaction tests, or market research. *Id.* at 1489, *citing Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 695 (2d Cir. 1994).

III. Ethex's Marketing of Pangestyme

Solvay contends that Ethex falsely marketed Pangestyme as an "alternative" substitute for Creon to wholesalers, chains, distributors, mail order houses, independent pharmacies, and managed health care organizations. Solvay further alleges that Ethex is marketing its Pangestyme line of products either expressly or by implication as "generic"

versions of Creon, although Solvay asserts that Pangestyme is not, in fact, an alternative to Creon.

The Court finds that there are numerous disputed issues of material fact as to whether Ethex's advertising is literally true. For example, Solvay asserts that Ethex's advertising makes false claims regarding Pangestyme's active ingredients and performance, which are material to a purchaser's decision in determining whether to purchase a drug. Ethex's labeling states that Pangestyme contains the same amount of active ingredients as Creon. However, Solvay offers evidence tending to show that, in contrast to Ethex's labeling, Pangestyme does not in fact contain the same amounts of active ingredients as Creon.

Similarly, although it is undisputed that Ethex is marketing Pangestyme as an "alternative" to numerous name-brand supplements, and the labeling specifies that these supplements are specially formulated to match each name-brand drug, Solvay offers evidence showing that Ethex's supplements all contain exactly the same active ingredients. For example, Ethex promotes Pangestyme-CR20 as a substitute for Creon 20, and Pangestyme-UL20 as a substitute for Ultrase-MT20, another name-brand pancreatic enzyme supplement. However, Solvay claims that test results show that, despite the different names and labels, Pangestyme-CR20 and Pangestyme-UL20 are in fact identical, except for the color of the capsules.

In addition, Solvay argues that Ethex falsely advertises that Pangestyme meets "USP requirements," when in truth, it does not consistently meet those requirements. Under USP requirements, a pancreatic enzyme supplement must not contain more than

165% of the labeled amount of lipase, one of the active ingredients in the supplements. Solvay presents evidence that test results show that Pangestyme contains more than 165% of the labeled amount of lipase.

Moreover, Solvay also asserts that Ethex's statement that Pangestyme has a "release threshold" of pH 5.5 is false, and that testing of Pangestyme revealed that its release threshold is far lower. The release threshold refers to the pH at which the enzymes dissolve. To be useful, pancreatic enzyme supplements need to survive passage through the stomach, which has a very low pH, to the duodenum. Thus, if Pangestyme dissolves at a pH level that is significantly lower than 5.5, as Solvay contends test results have shown, then Pangestyme would dissolve in the stomach and would not pass to the duodenum.

Further, Solvay offers survey evidence tending to show that a majority of purchasers of pancreatic enzyme supplements – pharmacists – understood that Pangestyme was equivalent to Creon.

Ethex disputes Solvay's test results relating to Pangestyme's active ingredients and performance, and responds with similar forms of conflicting evidence. Ethex also disputes Solvay's interpretation of the pharmacist survey. Ethex contends that its evidence shows that its statements regarding Pangestyme's ingredients and performance are literally true.

Other courts have faced similar issues in cases involving Lanham Act claims against "generic" drugs, and have found genuine issues of material fact precluding summary judgment on the false advertising claims. *See Solvay Pharms. v. Global*

Pharms., 419 F. Supp. 2d 1133 (D. Minn. 2006); *Pediamed Pharms. v. Breckenridge*, 2006 WL 544525 (D. Md. Mar. 6, 2006); *Schwarz Pharma v. Breckenridge Pharm.*, 388 F. Supp. 2d 967; *Healthpoint Ltd. v. Ethex Corp.*, 2004 WL 2359420 (W.D. Tex. Jul. 14, 2004); *Ethex Corp. v. Warner Chilcott, Inc.*, 2000 WL 34617364 (E.D. Mo. Jun. 19, 2000). Here, as in those cases, the parties have presented conflicting evidence regarding the truth or falsity of "generic" drug advertising.

Specifically, Solvay and Ethex offer contradictory evidence regarding Ethex's advertising of Pangestyme, including whether Pangestyme and Creon contain the same active ingredients and perform similarly, as well as pharmacists' understanding of Ethex's advertising. The Court finds that these are fact issues that must be resolved by a jury, and therefore summary judgment is not appropriate.

This case will be placed on the Court's next available trial calendar.

ORDER

Based on the foregoing, all the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that defendants' Motion for Summary Judgment [Docket No. 123] is **DENIED**.

DATED: August 7, 2006
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge